IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Terran Biosciences, Inc.	Confirmation No.:
Serial No.:	17/989,673	Group No.:
Filing or 371(c) Date:	17 November 2022	Examiner:

Entitled: PHENETHYLAMINE COMPOUNDS SALTS, POLYMORPHIC FORMS AND METHODS OF USE THEREOF

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. U.S. provisional document application number 63/250,978 (Filing date 30 September 2021)
2. U.S. provisional document application number 63/184,703 (Filing date 05 May 2021)
3. EROWID (2020) “Ecstasy Tablet Gallery” Retrieved from 25 December 2020. URL: https://web.archive.org/web/20201225063007/https://erowid.org/chemicals/mdma/mdma_images_gallery1.shtml
4. EROWID (2007) “MDMA Dosage” Retrieved from 9 April 2007. URL: https://web.archive.org/web/20070409141435/https://erowid.org/chemicals/mdma/mdma_dose.shtml
5. EROWID (2007) “MDE Images” Retrieved from 6 June 2007. URL: https://web.archive.org/web/20070606024111/https://erowid.org/chemicals/mde/mde_images.shtml
6. SHULGIN (1990) “#106 MDE” Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060343/https://erowid.org/library/books_online/pihkal/pihkal106.shtml

7. SHULGIN (1990) “#109 MDMA” Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060354/https://erowid.org/library/books_online/pihkal/pihkal109.shtml
8. ZOOMGROOVE (2016) “Cuddle Puddle” Retrieved from 11 August 2016. URL: https://web.archive.org/web/20160811183800/https://erowid.org/experiences/exp.php?ID=91055
9. SHULGIN (1990) “#128 METHYL-J" Retrieved 13 March 2007. URL: https://web.archive.org/web/20070313060406/https://erowid.org/library/books_online/pihkal/pihkal128.shtml
10. MURPLE (2001) “First Encounter with Mbi Dibi” Retrieved from 17 October 2017. URL: https://web.archive.org/web/20121017041940/https://erowid.org/experiences/exp.php?ID=10514
11. U.S. provisional document application number 63/236,498 (Filing date 24 August 2021)
12. U.S. Pat. No. US10406123B2 “Binge behavior regulators” Published 10 September 2019.
13. WOLFSON (2020) “MDMA-assisted psychotherapy for treatment of anxiety and other psychological distress related to life-threatening illnesses: a randomized pilot study” Scientific Reports. Vol. 10:20442.
14. U.S. provisional document application number 63/137,615 (Filing date 14 January 2021)
15. CORKERY (2013) “MDAI (5,6-methylenedioxy-2-aminoindane; 6,7-dihydro-5H-cyclopenta[f][1,3]benzodioxol-6-amine; ‘sparkle’; ‘mindy’) toxicity: a brief overview and update” Human Psychopharmacology: Clinical and Experimental. Vol 28(4): 345-355.
16. PUBCHEM (2007) “5-Methoxy-2,3-dihydro-1H-inden-2-amine". PubChem CID: 12147687. Date generated: 7 February 2007. URL: https://pubchem.ncbi.nlm.nih.gov/compound/5-Methoxy-2_3-dihydro-1H-inden-2-amine
17. PUBCHEM (2006) “5,6-dimethoxy-2,3-dihydro-1H-inden-2-amine” PubChem CID: 11041623. Date generated: 26 October 2006. URL: https://pubchem.ncbi.nlm.nih.gov/compound/11041623
18. RENDLE (2013) “Powder diffraction data for methylenedioxymethylamphetamine hydrochloride monohydrate (MDMA.HCl.H2O, Ecstasy hydrate)” Powder Diffraction. Vol: 27(4): 263-265.
19. RESEARCHGATE (2014) “How can I convert the XRD pattern taken using Cobalt-K alpha to Copper-K alpha?” URL: https://www.researchgate.net/post/How-can-I-convert-the-XRD-pattern-taken-using-Cobalt-K-alpha-to-Copper-K-alpha

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 17/989,673 Pending Claims	References
1. A solid form of MDMA, (S)-MDMA, (R)-MDMA, MDE, (S)-MDE, (R)-MDE, MBDB, (S)-MBDB, (R)-MBDB, MDAI, MEAI, or 5,6-Dimethoxy-2-aminoindane.	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include **powders**, **tablets**, **pills**, capsules, cachets, suppositories, and dispersible granules."* 3. EROWID (2020) "Ecstasy Tablet Gallery" Retrieved from 25 December 2020. URL: https://web.archive.org/web/20201225063007/https://erowid.org/chemicals/mdma/mdma_images_gallery1.shtml From **page 1** "Black market **ecstasy tablets** generally bear an imprint designed to identify and distinguish a particular 'brand'" From **page 1** 

	7. SHULGIN (1990) "#109 MDMA" Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060354/https://erowid.org/library/books_online/pihkal/pihkal109.shtml From **page 1** "On continued stirring, there was the deposition of **fine white crystals of 3,4-methylenedioxy-N-methylamphetamine hydrochloride (MDMA)** which were removed by filtration, washed with Et2O, and **air dried**, giving a final weight of 4.8 g." From **page 2** "(with 100 mg of the **"R" isomer**) There were the slightest of effects noted at about an hour (a couple of paresthetic twinges) and then nothing at all." From **page 2** "(with 100 mg of the **"S" isomer**) I feel the onset is slower than with the racemate. Physically, I am excited, and my pulse and blood pressure are quite elevated. This does not have the 'fire' of the racemate, nor the rush of the development in getting to the plateau." 1. U.S. provisional document application number 63/250,978 (Filing date 30 September 2021) From **PDF page 12, paragraph [0003]** "In one aspect, the present disclosure provides **pharmaceutical compositions containing a non-racemic mixture of (R)-3,4-methylenedioxymethamphetamine (MDMA) or a pharmaceutically acceptable salt thereof and (S)-MDMA** or pharmaceutically acceptable salt thereof" From **PDF page 13, PDF page 18, paragraph [0010]** "In embodiments, the composition of the present disclosure is an oral dosage form. In some embodiments, the **oral dosage form is a tablet or capsule**." From **PDF page 23, paragraph [0065]** "**Oral pharmaceutical dosage forms can be either solid** or liquid. **The solid dosage forms can be tablets, capsules, granules,** films, (e.g. buccal films) **and bulk powders**." 2. U.S. provisional document application number 63/184,703 (Filing date 05 May 2021) From **PDF page 18, paragraph [0011]** "The present invention provides for **compositions of enantiomers of MDMA** or MDA that are useful in psychotherapeutic or medical treatment. Most preferably, the composition is an **R(-) enantiomer of MDMA** or MDA."

	From **PDF page 21, paragraph [0019]** "The **composition can be in a solid dosage form** such as but not limited to, capsules, films, lozenges, patch, **powder, tablets, pellets, pills,** or troches"
2. The solid form of claim 1, wherein the solid form is a solid form of MDMA.	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include powders, **tablets**, pills, capsules, cachets, suppositories, and dispersible granules."* 3. EROWID (2020) "Ecstasy Tablet Gallery" Retrieved from 25 December 2020. URL: https://web.archive.org/web/20201225063007/https://erowid.org/chemicals/mdma/mdma_images_gallery1.shtml From **page 1** "Black market **ecstasy tablets** generally bear an imprint designed to identify and distinguish a particular 'brand'" From **page 1** 

	4. EROWID (2007) “MDMA Dosage” Retrieved from 9 April 2007. URL: https://web.archive.org/web/20070409141435/https://erowid.org/chemicals/mdma/mdma_dose.shtml From **page 1** “**MDMA generally comes in the form of small tablets, capsules, or white powder**. When found in tablet form (often referred to as "ecstasy"), it is common for MDMA to be combined with any of the following substances : MDMA, Caffeine, MDA, Methamphetamine, DXM, MDE, Pseudo/Ephedrine, Ketamine, BZP, and TFMPP. Chemical analysis of ecstasy tablets has found from 0 - 120 mg of MDMA as well as a variety of the above substances. Trying to calculate dosages from tablets containing unknown quantities of MDMA can be difficult, but a high quality tablet of street ecstasy (those containing MDMA alone) generally contains between 80 and 120 mg of MDMA. Some unusual tablets (especially in Europe) contain 150mg or more. The chart below shows what are considered recreational/therapeutic **dosages for pure MDMA HCl (the most common crystalline form)**, measured in milligrams.” 7. SHULGIN (1990) “#109 MDMA” Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060354/https://erowid.org/library/books_online/pihkal/pihkal109.shtml From **page 1** “On continued stirring, there was the deposition of **fine white crystals of 3,4-methylenedioxy-N-methylamphetamine hydrochloride (MDMA)** which were removed by filtration, washed with Et2O, and **air dried**, giving a final weight of 4.8 g.” From **page 2** “In one study, **MDMA was consumed** at 9:00 AM each day for almost a week (120 milligrams the first day and 160 milligrams each subsequent day) and by the fifth day there were no effects from the drug except for some mydriasis.” From **page 2** “(with 100 mg of the **"R" isomer**) There were the slightest of effects noted at about an hour (a couple of paresthetic twinges) and then nothing at all.” From **page 2** “(with 100 mg of the **"S" isomer**) I feel the onset is slower than with the racemate. Physically, I am excited, and my pulse and blood pressure are quite elevated. This does not have the 'fire' of the racemate, nor the rush of the development in getting to the plateau.”
3. The solid form of MDMA of claim 2, wherein the solid form of MDMA is a salt of MDMA.	4. EROWID (2007) “MDMA Dosage” Retrieved from 9 April 2007. URL: https://web.archive.org/web/20070409141435/https://erowid.org/chemicals/mdma/mdma_dose.shtml

	From **page 1** "**MDMA generally comes in the form of small tablets, capsules, or white powder**. When found in tablet form (often referred to as "ecstasy"), it is common for MDMA to be combined with any of the following substances : MDMA, Caffeine, MDA, Methamphetamine, DXM, MDE, Pseudo/Ephedrine, Ketamine, BZP, and TFMPP. Chemical analysis of ecstasy tablets has found from 0 - 120 mg of MDMA as well as a variety of the above substances. Trying to calculate dosages from tablets containing unknown quantities of MDMA can be difficult, but a high quality tablet of street ecstasy (those containing MDMA alone) generally contains between 80 and 120 mg of MDMA. Some unusual tablets (especially in Europe) contain 150mg or more. The chart below shows what are considered recreational/therapeutic **dosages for pure MDMA HCl (the most common crystalline form)**, measured in milligrams."
4. The salt of MDMA of claim 3, wherein the salt of MDMA is a crystalline salt of MDMA, optionally: a) a solid form of MDMA fumarate Form 1, further optionally a crystalline polymorph of MDMA fumarate characterized by two or more, or three or more XRPD signals selected from the group consisting of 17.3°2θ, 18.6°2θ, and 21.9°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); b) a solid form of MDMA fumarate Form 2; further optionally a crystalline polymorph of MDMA fumarate characterized by two or more, or three or more XRPD signals selected from the group consisting of 14.5°2θ, 22.2°2θ, and 27.3°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);	4. EROWID (2007) "MDMA Dosage" Retrieved from 9 April 2007. URL: https://web.archive.org/web/20070409141435/https://erowid.org/chemicals/mdma/mdma_dose.shtml From **page 1** "**MDMA generally comes in the form of small tablets, capsules, or white powder**. When found in tablet form (often referred to as "ecstasy"), it is common for MDMA to be combined with any of the following substances : MDMA, Caffeine, MDA, Methamphetamine, DXM, MDE, Pseudo/Ephedrine, Ketamine, BZP, and TFMPP. Chemical analysis of ecstasy tablets has found from 0 - 120 mg of MDMA as well as a variety of the above substances. Trying to calculate dosages from tablets containing unknown quantities of MDMA can be difficult, but a high quality tablet of street ecstasy (those containing MDMA alone) generally contains between 80 and 120 mg of MDMA. Some unusual tablets (especially in Europe) contain 150mg or more. The chart below shows what are considered recreational/therapeutic **dosages for pure MDMA HCl (the most common crystalline form)**, measured in milligrams." 7. SHULGIN (1990) "#109 MDMA" Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060354/https://erowid.org/library/books_online/pihkal/pihkal109.shtml From **page 1** "On continued stirring, there was the deposition of **fine white crystals of** 3**,4-methylenedioxy-N-methylamphetamine hydrochloride (MDMA) which were removed by filtration**, washed with Et2O, **and air dried**, giving a final weight of 4.8 g." 18. RENDLE (2013) "Powder diffraction data for methylenedioxymethylamphetamine hydrochloride monohydrate (MDMA.HCl.H2O, Ecstasy hydrate)" Powder Diffraction. Vol: 27(4): 263-265.

c) a solid form of MDMA maleate Form 1; further optionally a crystalline polymorph of MDMA maleate characterized by two or more, or three or more XRPD signals selected from the group consisting of 14.9°2θ, 18.1°2θ, and 25.0°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);
d) a solid form of MDMA maleate Form 2; further optionally a crystalline polymorph of MDMA maleate characterized by two or more, or three or more XRPD signals selected from the group consisting of 9.4°2θ, 18.5°2θ, and 26.8°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);
e) a solid form of MDMA phosphate; further optionally a crystalline polymorph of MDMA phosphate characterized by two or more, or three or more XRPD signals selected from the group consisting of 12.4°2θ, 19.0°2θ, and 22.0°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);
f) a solid form of MDMA tartrate; further optionally a crystalline polymorph of MDMA tartrate characterized by

From 263 "**X-ray data were collected using a Philips PW1050/37 vertical diffractometer in θ/2θ mode with Fe-filtered CoKα radiation** (λ = 1.78897 Å) from a Philips long fine focus tube powered at 35 kV and 42 mA"

From page 264

TABLE I. XRD data for MDMA.HCl.H_2O (Co$K\alpha$).

$2\theta_{obs}$	d_{obs}	I_{obs}	$h\ k\ l$	$2\theta_{cal}$	d_{cal}	$\Delta 2\theta$
9.879	10.388	14	0 2 0	9.898	10.369	−0.019
12.819	8.013	19	0 1 1	12.803	8.023	0.016
15.409	6.672	33	0 2 1	15.414	6.670	−0.005
15.789	6.512	290	1 1 0	15.775	6.518	0.014
15.909	6.464	206	−1 0 1	15.907	6.464	0.002
16.659	6.174	97	−1 1 1	16.664	6.173	−0.005
17.969	5.728	112	1 2 0	17.967	5.728	0.002
18.749	5.491	426	−1 2 1	18.755	5.490	−0.006
18.989	5.423	225	0 3 1	18.999	5.420	−0.010
19.829	5.195	20	0 4 0	19.833	5.194	−0.004
21.119	4.881	26	1 3 0	21.135	4.877	−0.016
21.809	4.728	638	1 0 1	21.838	4.722	−0.029
22.399	4.605	403	1 1 1	22.401	4.605	−0.002
23.129	4.462	306	0 4 1	23.129	4.462	0.000
23.719	4.352	999	0 0 2	23.704	4.355	0.015
24.239	4.260	684	−1 1 2	24.280	4.253	−0.041
24.939	4.143	16	1 4 0	24.928	4.144	0.011
25.759	4.013	317	−1 2 2	25.783	4.009	−0.024

19. RESEARCHGATE (2014) "How can I convert the XRD pattern taken using Cobalt-K alpha to Copper-K alpha?" URL: https://www.researchgate.net/post/How-can-I-convert-the-XRD-pattern-taken-using-Cobalt-K-alpha-to-Copper-K-alpha

From page 1 "I recorded XRD pattern using Cobalt-K alpha, but I have the PANalytical software with data base which was with Cu-K ALPHA radiation. Using POWDLL, I cannot convert it. Can you **help me convert XRD pattern from Co-K alpha to Cu-K alpha**?"

From page 1 "I am agree with Prof. Elies Molinsagree suggestion. This is not doing the experiment again using CuKa radiation. So, **you have to find out the new peak positions using CuKa radiation**. Since, "d" is fixed for the sample for a particular plan, we have to play with the wavelengths and diffraction angles.

two or more, or three or more XRPD signals selected from the group consisting of 12.5°2θ, 18.0°2θ, and 18.3°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); g) a solid form of MDMA tartrate; further optionally a crystalline polymorph of MDMA tartrate characterized by two or more, or three or more XRPD signals selected from the group consisting of 5.2°2θ, 18.9°2θ, and 19.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); h) a solid form of MDMA malate; further optionally a crystalline polymorph of MDMA malate characterized by two or more, or three or more XRPD signals selected from the group consisting of 17.2°2θ, 18.0°2θ, and 19.2°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); i) a solid form of MDMA galactarate; further optionally a crystalline polymorph of MDMA galactarate characterized by two or more, or three or more XRPD signals selected from the group consisting of 4.6°2θ, 18.8°2θ, and 19.6°2θ (±0.2°2θ; ±0.1°2θ; or	**New peak position(2Theta) :- Sin Theta(Cu)/2 =(1.5406/1.7959) x Sin Theta (Co)/2** **= Sin Theta(Cu)/2 = 0.858 x Sin Theta (Co)/2**”

±0.0°2θ; Cu Kα1 radiation); j) a solid form of MDMA succinate; further optionally a crystalline polymorph of MDMA succinate characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.0°2θ, 21.8°2θ, and 22.2°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); k) a solid form of MDMA tosylate; further optionally a crystalline polymorph of MDMA tosylate characterized by two or more, or three or more XRPD signals selected from the group consisting of 15.4°2θ, 20.5°2θ, and 21.9°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); **l) a solid form of MDMA HCl; further optionally a crystalline polymorph of MDMA HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 15.9°2θ, 18.5°2θ, and 21.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);** m) a solid form of MDMA hemifumarate Form A; further optionally a crystalline	

polymorph of MDMA hemifumarate Form A characterized by two or more, or three or more XRPD signals selected from the group consisting of 8.3°2θ, 10.9°2θ, and 13.0°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); n) a solid form of (S)-MDMA HCl; further optionally a crystalline polymorph of (S)-MDMA HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 15.7°2θ, 17.4°2θ, and 20.6°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); o) a solid form of (R)-MDMA HCl; further optionally a crystalline polymorph of (R)-MDMA HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 15.7°2θ, 17.4°2θ, and 20.6°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation).	
5.- 18. (canceled)	
19. A mixture of solid forms of a salt of MDMA, the mixture comprising: a) crystalline polymorphs of MDMA fumarate Forms 1 and 2	11. U.S. provisional document application number 63/236,498 (Filing date 24 August 2021) From **PDF page 23, paragraph [00022]** "**Psychoactive base substances to be used in the present invention include** or MDMA-like substances such as, but not limited to, **MDMA**, MDA, MDEA, MBDB, BDB, MDB,….."

characterized by a XRPD diffractogram substantially similar to that shown in FIG. 10; or b) crystalline polymorphs of MDMA tartrate Forms 1 and 2 characterized by a XRPD diffractogram substantially similar to that shown in FIG. 12.	From **PDF page 23, paragraph [00023]** "...**Therefore, they form pharmaceutically acceptable inorganic and organic salts with pharmacologically acceptable inorganic or organic acids**. **Acids to form such salts can be selected from** inorganic acids such as hydrochloric acid, hydrobromic acid, hyroiodic acid, sulfuric acid, nitric acid, phosphoric acid, and the like, organic acids such as carbonic acid, p-toluenesulfonic acid methanesulfonic acid, oxalic acid, succinic acid, **citric acid**...**Examples of such pharmaceutically acceptable salts thus are...fumarate**...**tartrate**..."
20.- 111. (canceled)	
112. The solid form of claim 1, wherein the solid form is a solid form of MDE; optionally a salt of MDE; further optionally a crystalline salt of MDE.	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include **powders**, **tablets**, pills, capsules, cachets, suppositories, and dispersible granules."* 5. EROWID (2020) "MDE Images" Retrieved from 6 June 2007. URL: https://web.archive.org/web/20070606024111/https://erowid.org/chemicals/mde/mde_images.shtml From **page 1** "Color photo of 2 **MDE tablets** with a penny for size comparison." 6. SHULGIN (1990) "#106 MDE" Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060343/https://erowid.org/library/books_online/pihkal/pihkal106.shtml From **page 1** "The crystalline product was removed by filtration, washed with 80% Et2O (containing IPA) followed by Et2O itself, and then air dried to provide 3.0 g of **3,4-methylenedioxy-N-ethylamphetamine hydrochloride (MDE) as fine white crystals** with a mp of 198-199 °C."
113.- 114. (canceled)	
115. The crystalline salt of MDE of claim 112, wherein the crystalline salt is: a) MDE HCl; further optionally a crystalline polymorph of MDE HCl characterized by XRPD signals at 15.6°2θ and 21.6°2θ (±0.2°2θ; ±0.1°2θ; or	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include **powders**, tablets, pills, capsules, cachets, suppositories, and dispersible granules."* 6. SHULGIN (1990) "#106 MDE" Retrieved from 13 March 2007. URL: https://web.archive.org/web/20070313060343/https://erowid.org/library/books_online/pihkal/pihkal106.shtml From **page 1** "The crystalline product was removed by filtration, washed with 80% Et2O (containing IPA) followed by Et2O itself, and then **air dried**

±0.0°2θ; Cu Kα1 radiation); b) (R)-MDE HCl; further optionally a crystalline polymorph of (R)-MDE HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 14.5°2θ, 17.0°2θ, and 22.2°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); c) (S)-MDE HCl; further optionally a crystalline polymorph of (S)-MDE HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 14.5°2θ, 27.6°2θ, and 31.8°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); or d) (S)-MDE tosylate; further optionally a crystalline polymorph of (S)-MDE tosylate characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.9°2θ, 19.8°2θ, and 21.8°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation).	to provide 3.0 g of **3,4-methylenedioxy-N-ethylamphetamine hydrochloride (MDE) as fine white crystals** with a mp of 198-199 °C."
116- 143. (canceled)	
144. The solid form of claim 1, wherein the solid form is a solid form of MDAI; optionally a salt of	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include powders, tablets, pills, capsules, cachets, suppositories, and dispersible granules."*

MDAI; further optionally a crystalline salt of MDAI.	8. ZOOMGROOVE (2016) "Cuddle Puddle" Retrieved from 11 August 2016. URL: https://web.archive.org/web/20160811183800/https://erowid.org/experiences/exp.php?ID=91055 From **page 1**  15. CORKERY (2013) "MDAI (5,6-methylenedioxy-2-aminoindane; 6,7-dihydro-5H-cyclopenta[f][1,3]benzodioxol-6-amine; 'sparkle'; 'mindy') toxicity: a brief overview and update" Human Psychopharmacology: Clinical and Experimental. Vol 28(4): 345-355. From **page 347** "There are **several known routes of MDAI administration**: insufflation (snorting, sniffing), **oral** (wrapped in a cigarette paper 'bomb', or swallowed **in the form of a capsule/pellet/pill)** and rectal (plugging, or dissolving the substance in alcohol and applying it as an enema)."
145.- 146. (canceled)	
147. The crystalline salt of MDAI of claim 144, wherein the crystalline salt is solid form of MDAI HCl; further optionally a crystalline polymorph of MDAI	11. U.S. provisional document application number 63/236,498 (Filing date 24 August 2021) From **PDF page 23, paragraph [00022]** "**Psychoactive base substances to be used in the present invention include** or MDMA-like substances such as, but not limited to, MDMA, MDA, MDEA, MBDB, BDB, MDB, 2F-MDA, 5F-MDA, 6F-MDA, ethylone, **MDAI,**….."

HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 16.9°2θ, 23.6°2θ, and 24.2°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation).	From **PDF page 23, paragraph [00023]** "...**Therefore, they form pharmaceutically acceptable inorganic and organic salts with pharmacologically acceptable inorganic or organic acids**. **Acids to form such salts can be selected from inorganic acids such as hydrochloric acid**, hydrobromic acid, hyroiodic acid, sulfuric acid, nitric acid, phosphoric acid, and the like, organic acids such as carbonic acid, p-toluenesulfonic acid methanesulfonic acid, oxalic acid, succinic acid, citric acid...Examples of such pharmaceutically acceptable salts thus are...citrate..." 15. CORKERY (2013) "MDAI (5,6-methylenedioxy-2-aminoindane; 6,7-dihydro-5H-cyclopenta[f][1,3]benzodioxol-6-amine; 'sparkle'; 'mindy') toxicity: a brief overview and update" Human Psychopharmacology: Clinical and Experimental. Vol 28(4): 345-355. From **page 347** "There are **several known routes of MDAI administration**: insufflation (snorting, sniffing), **oral** (wrapped in a cigarette paper 'bomb', or swallowed **in the form of a capsule/pellet/pill)** and rectal (plugging, or dissolving the substance in alcohol and applying it as an enema)."
148.- 157. (canceled)	
158. The solid form of claim 1, wherein the solid form is a solid form of MBDB; optionally a salt of MBDB; further optionally a crystalline salt of MBDB.	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include **powders**, tablets, pills, capsules, cachets, suppositories, and dispersible granules."* 9. SHULGIN (1990) "#128 METHYL-J" Retrieved 13 March 2007. URL: https://web.archive.org/web/20070313060406/https://erowid.org/library/books_online/pihkal/pihkal128.shtml From **page 1** "#128 METHYL-J **MBDB**; EDEN; 2-METHYLAMINO-1-(3,4-METHYLENEDIOXYPHENYL)BUTANE; N-METHYL-1-(1,3-BENZODIOXOL-5-YL)-2-BUTANAMINE" From **page 1** "The **solids that separated were removed by filtration, Et2O washed, and air dried to provide 6.07 g 2-methylamino-1-(3,4-methylenedioxyphenyl)butane hydrochloride (METHYL-J or MBDB) as white crystals** with a mp of 156 °C. Anal. (C12H18ClNO2) C,H,N. Reductive amination of the butanone with methylamine hydrochloride in MeOH, employing sodium cyano-borohydride, gave an identical product but in a smaller yield."

	10. MURPLE (2001) "First Encounter with Mbi Dibi" Retrieved from 17 October 2017. URL: https://web.archive.org/web/20121017041940/https://erowid.org/experiences/exp.php?ID=10514 
161. The crystalline salt of MBDB of claim 158, wherein the crystalline salt is: a) MBDB citrate; further optionally a crystalline polymorph of MBDB citrate characterized by two or more, or three or more XRPD signals selected from the group consisting of 6.3°2θ, 19.0°2θ, and 25.4°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); b) MBDB fumarate; further optionally a crystalline polymorph of MBDB fumarate characterized by two or more, or three or more	11. U.S. provisional document application number 63/236,498 (Filing date 24 August 2021) From **PDF page 23, paragraph [00022]** "**Psychoactive base substances to be used in the present invention include** or MDMA-like substances such as, but not limited to, MDMA, MDA, MDEA, **MBDB**, BDB, MDB,….." From **PDF page 23, paragraph [00023]** "...**Therefore, they form pharmaceutically acceptable inorganic and organic salts with pharmacologically acceptable inorganic or organic acids**. **Acids to form such salts can be selected from** inorganic acids such as hydrochloric acid, hydrobromic acid, hyroiodic acid, sulfuric acid, nitric acid, phosphoric acid, and the like, organic acids such as carbonic acid, p-toluenesulfonic acid methanesulfonic acid, oxalic acid, succinic acid, **citric acid**...**Examples of such pharmaceutically acceptable salts thus are...citrate**..."

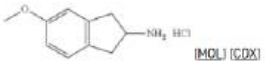
XRPD signals selected from the group consisting of 12.9°2θ, 20.2°2θ, and 20.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); c) MBDB fumarate; further optionally a crystalline polymorph of MBDB fumarate characterized by two or more, or three or more XRPD signals selected from the group consisting of 12.9°2θ, 20.2°2θ, and 20.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); d) MBDB galactarate; further optionally a crystalline polymorph of MBDB galactarate characterized by two or more, or three or more XRPD signals selected from the group consisting of 9.2°2θ, 19.6°2θ, and 23.1°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); e) MBDB maleate Form 1; further optionally a crystalline polymorph of MBDB maleate Form 1 characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.8°2θ, 22.4°2θ, and 23.8°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);	

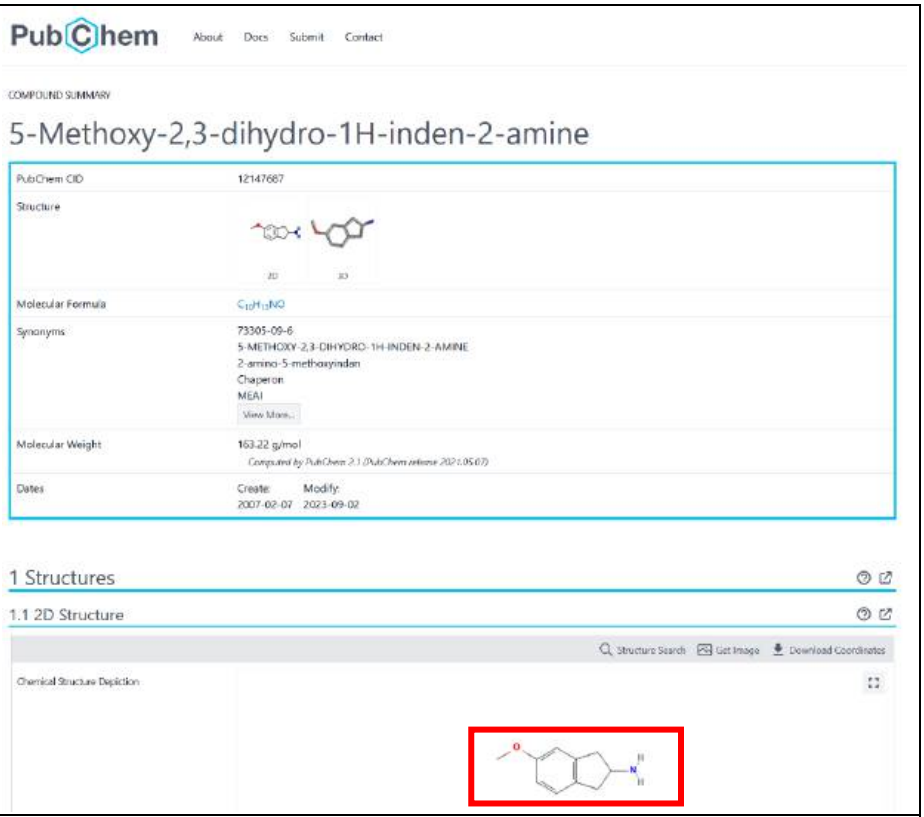
f) MBDB maleate Form 2; further optionally a crystalline polymorph of MBDB maleate Form 2 characterized by two or more, or three or more XRPD signals selected from the group consisting of 9.7°2θ, 11.8°2θ, and 14.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); g) MBDB maleate Form 2; further optionally a crystalline polymorph of MBDB maleate Form 2 characterized by two or more, or three or more XRPD signals selected from the group consisting of 9.3°2θ, 9.7°2θ, and 10.9°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); h) MBDB phosphate; further optionally a crystalline polymorph of MBDB phosphate characterized by two or more, or three or more XRPD signals selected from the group consisting of 6.4°2θ, 12.7°2θ, and 21.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); i) MBDB succinate Form 1; further optionally a crystalline polymorph of MBDB succinate Form 1 characterized by two or more, or three or more XRPD signals selected	

from the group consisting of 13.1°2θ, 20.5°2θ, and 21.9°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); j) MBDB succinate Form 2; further optionally a crystalline polymorph of MBDB succinate Form 2 characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.0°2θ, 20.3°2θ, and 21.5°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); k) MBDB sulfate; further optionally a crystalline polymorph of MBDB sulfate characterized by two or more, or three or more XRPD signals selected from the group consisting of 8.8°2θ, 17.5°2θ, and 26.4°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); l) MBDB tartrate; further optionally a crystalline polymorph of MBDB tartrate characterized by two or more, or three or more XRPD signals selected from the group consisting of 5.8°2θ, 11.5°2θ, and 17.2°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation);	

m) MBDB malonate; further optionally a crystalline polymorph of MBDB malonate characterized by two or more, or three or more XRPD signals selected from the group consisting of 18.1°2θ, 20.4°2θ, and 22.7°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); n) MBDB tosylate; further optionally a crystalline polymorph of MBDB tosylate characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.1°2θ, 18.1°2θ, and 19.1°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); o) MBDB HCl Form A; further optionally a crystalline polymorph of MBDB HCl Form A characterized by two or more, or three or more XRPD signals selected from the group consisting of 14.3°2θ, 14.9°2θ, and 25.4°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); p) MBDB HCl Form B; further optionally a crystalline polymorph of MBDB HCl Form B characterized by two or more, or three or more XRPD signals selected from the group	

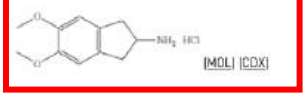
consisting of 19.7°2θ, 25.0°2θ, and 30.7°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); q) MBDB HCl Form A; further optionally a crystalline polymorph of MBDB HCl Form A characterized by two or more, or three or more XRPD signals selected from the group consisting of 16.7°2θ, 18.4°2θ, and 19.6°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); r) (R)-MBDB HCl; further optionally a crystalline polymorph of (R)-MBDB HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.2°2θ, 14.1°2θ, and 16.7°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation); or s) (S)-MBDB HCl; further optionally a crystalline polymorph of (S)-MBDB HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 13.3°2θ, 16.7°2θ, and 19.6°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation).	
162.- 325. (canceled)	
326. The solid form of claim 1, wherein the	*From the application of interest 17/989,673 paragraph [0004] "N-methyl-3,4-methylenedioxyamphetamine (MDMA), (R)-MDMA, (S)-MDMA, N-*

solid form is a solid form of MEAI; optionally a salt of MEAI; further optionally a crystalline salt of MEAI.	*ethyl-3,4-methylenedioxyamphetamine hydrochloride (MDE), 5,6-methylenedioxy-2-aminoindane (MDAI), N-methyl-1,3-benzodioxolylbutanamine (MBDB),* ***5-Methoxy-2-aminoindane (MEAI)****, and 5,6-Dimethoxy-2-aminoindane are synthetic analogues of the psychedelic phenethylamine class of compounds. Solid forms of MDMA, (R)-MDMA, (S)-MDMA, MDE, S-MDE, R-MDE, MDAI, MBDB, S-MBDB, R-MBDB, MEAI, or 5,6-Dimethoxy-2-aminoindane, and salts thereof having improved properties are disclosed herein."* *From the application of interest 17/989,673 paragraph [0160]* "5-Methoxy-2-aminoindane hydrochloride" as used herein refers to the racemic compound 5-methoxy-2,3-dihydro-1H-inden-2-amine hydrochloride. The compound also may be referred to as 2-amino-5-methoxyindan hydrochloride, 5-methoxyindan-2-ylamine hydrochloride, MEAI HCl, or 5-MeO-AI HCl.  [MCL] [CDX] 5-Methoxy-2-aminoindane hydrochloride 12. U.S. Pat. No. US10406123B2 "Binge behavior regulators" Published 10 September 2019. From **page 6, column 8, paragraph 2**"According to some of any of the embodiments of the present invention, **the compound of Formula I is** selected from: **5-methoxy-2-aminoindan**; and 5,6-dimethoxy-2-aminoindan." From **page 14, column 24, paragraph 3** "**Pharmaceutical compositions comprising the compound of Formula I as described herein, may be administered systemically in oral solid** or oral liquid formulations, or as suppository, aerosol, topical or other similar formulations. In preferred embodiments, the binge regulator or a composition comprising same is administered to a subject orally." 16. PUBCHEM (2007) "5-Methoxy-2,3-dihydro-1H-inden-2-amine". PubChem CID: 12147687. Date generated: 7 February 2007. URL: https://pubchem.ncbi.nlm.nih.gov/compound/5-Methoxy-2_3-dihydro-1H-inden-2-amine From page 1

	
327.- 328. (canceled)	
329. The crystalline salt of MEAI of claim 326, wherein the crystalline salt is MEAI HCl; further optionally a crystalline polymorph of MEAI HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 21.6°2θ, 21.7°2θ, and 32.7°2θ (±0.2°2θ; ±0.1°2θ; or ±0.0°2θ; Cu Kα1 radiation).	*From the application of interest 17/989,673 paragraph [0004] "N-methyl-3,4-methylenedioxyamphetamine (MDMA), (R)-MDMA, (S)-MDMA, N-ethyl-3,4-methylenedioxyamphetamine hydrochloride (MDE), 5,6-methylenedioxy-2-aminoindane (MDAI), N-methyl-1,3-benzodioxolylbutanamine (MBDB),* ***5-Methoxy-2-aminoindane (MEAI)****, and 5,6-Dimethoxy-2-aminoindane are synthetic analogues of the psychedelic phenethylamine class of compounds. Solid forms of MDMA, (R)-MDMA, (S)-MDMA, MDE, S-MDE, R-MDE, MDAI, MBDB, S-MBDB, R-MBDB, MEAI, or 5,6-Dimethoxy-2-aminoindane, and salts thereof having improved properties are disclosed herein."* 12. U.S. Pat. No. US10406123B2 "Binge behavior regulators" Published 10 September 2019. From **page 6, column 8, paragraph 2** "According to some of any of the embodiments of the present invention, **the compound of Formula I is** selected from: **5-methoxy-2-aminoindan**; and 5,6-dimethoxy-2-aminoindan." From **page 14, column 24, paragraph 3** "**Pharmaceutical compositions comprising the compound of Formula I as described herein, may be administered systemically in oral solid** or oral liquid formulations, or as

	suppository, aerosol, topical or other similar formulations. In preferred embodiments, the binge regulator or a composition comprising same is administered to a subject orally." From **page 13, column 21, paragraph 1** "In any one of the embodiments described herein, each of the compounds described herein can further be in a form of a **pharmaceutically acceptable salt** thereof." From **page 13, column 21, paragraph 2** "As used herein, the phrase **"pharmaceutically acceptable salt"** refers to a charged species of the parent compound and its counter-ion, which is typically used to modify the solubility characteristics of the parent compound and/or to reduce any significant irritation to an organism by the parent compound, while not abrogating the biological activity and properties of the administered compound." From **page 13, column 21, paragraph 3** "In the context of some of the present embodiments, **a pharmaceutically acceptable salt of the compounds described herein may optionally be an acid addition salt** comprising at least one basic (e.g., amine) group of the compound which is in a positively charged form (e.g., an ammonium ion), in combination with at least one counter-ion, derived from the selected acid, that forms a pharmaceutically acceptable salt." From **page 13, column 22, paragraph 1** "The **acid addition salts may include** a variety of organic and inorganic acids, such as, **but not limited to, hydrochloric acid which affords a hydrochloric acid addition salt,**..."
330.- 332. (canceled)	
333. The solid form of claim 1, wherein the solid form is a solid form of 5,6-dimethoxy-2-aminoindane; optionally a salt of 5,6-dimethoxy-2-aminoindane; further optionally a crystalline salt of 5,6-dimethoxy-2-aminoindane.	*From the application of interest 17/989,673 paragraph [0004] "N-methyl-3,4-methylenedioxyamphetamine (MDMA), (R)-MDMA, (S)-MDMA, N-ethyl-3,4-methylenedioxyamphetamine hydrochloride (MDE),* ***5,6-****methylenedioxy-2-aminoindane (MDAI), N-methyl-1,3-benzodioxolylbutanamine (MBDB), 5-Methoxy-2-aminoindane (MEAI), and* ***5,6-Dimethoxy-2-aminoindane*** *are synthetic analogues of the psychedelic phenethylamine class of compounds. Solid forms of MDMA, (R)-MDMA, (S)-MDMA, MDE, S-MDE, R-MDE, MDAI, MBDB, S-MBDB, R-MBDB, MEAI, or 5,6-Dimethoxy-2-aminoindane, and salts thereof having improved properties are disclosed herein."* *From the application of interest 17/989,673 paragraph [0161]*

"5,6-Dimethoxy-2-aminoindane hydrochloride" as used herein refers to the compound 5,6-dimethoxy-2,3-dihydro-1H-inden-2-amine hydrochloride. The compound also may be referred to as 5,6-dimethoxyindan-2-amine hydrochloride, 2-amino-5,6-dimethoxyindan hydrochloride, or 5,6-dimethoxyindan-2-ylamine hydrochloride.



[MOL] [CDX]

5,6-Dimethoxy-2-aminoindane hydrochloride

12. U.S. Pat. No. US10406123B2 “Binge behavior regulators” Published 10 September 2019.

From **page 6, column 8, paragraph 2** “According to some of any of the embodiments of the present invention, **the compound of Formula I is** selected from: 5-methoxy-2-aminoindan; and **5,6-dimethoxy-2-aminoindan**.”

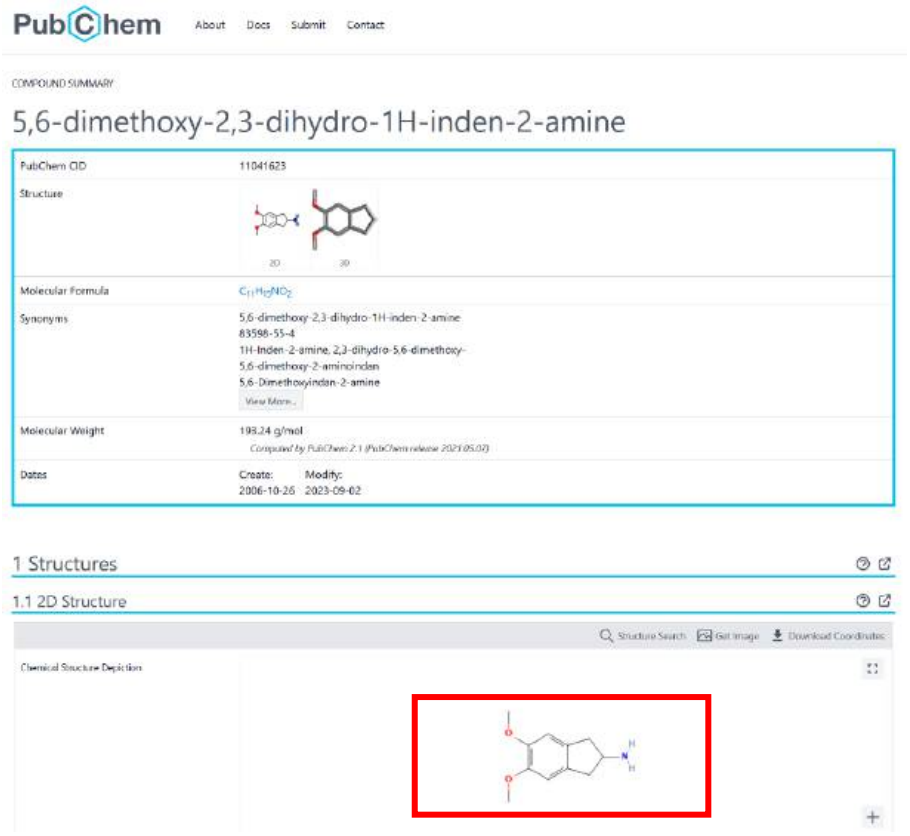
From **page 14, column 24, paragraph 3** “**Pharmaceutical compositions comprising the compound of Formula I as described herein, may be administered systemically in oral solid** or oral liquid formulations, or as suppository, aerosol, topical or other similar formulations. In preferred embodiments, the binge regulator or a composition comprising same is administered to a subject orally.”

From **page 13, column 21, paragraph 1** “In any one of the embodiments described herein, each of the compounds described herein can further be in a form of a **pharmaceutically acceptable salt** thereof.”

From **page 13, column 21, paragraph 2** “As used herein, the phrase **“pharmaceutically acceptable salt”** refers to a charged species of the parent compound and its counter-ion, which is typically used to modify the solubility characteristics of the parent compound and/or to reduce any significant irritation to an organism by the parent compound, while not abrogating the biological activity and properties of the administered compound.”

From **page 13, column 21, paragraph 3** “In the context of some of the present embodiments, **a pharmaceutically acceptable salt of the compounds described herein may optionally be an acid addition salt** comprising at least one basic (e.g., amine) group of the compound which is in a positively charged form (e.g., an ammonium ion), in combination with at least one counter-ion, derived from the selected acid, that forms a pharmaceutically acceptable salt.”

From **page 13, column 22, paragraph 1** “The **acid addition salts may include** a variety of organic and inorganic acids, such as, **but not limited to, hydrochloric acid which affords a hydrochloric acid addition salt,**...”

	17. PUBCHEM (2006) "5,6-dimethoxy-2,3-dihydro-1H-inden-2-amine" PubChem CID: 11041623. Date generated: 26 October 2006. URL: https://pubchem.ncbi.nlm.nih.gov/compound/11041623 
334.- 335. (canceled)	
336. The crystalline salt of 5,6-dimethoxy-2-aminoindane of claim 333, wherein the crystalline salt is 5,6-dimethoxy-2-aminoindane HCl further optionally a crystalline polymorph of 5,6-dimethoxy-2-aminoindane HCl characterized by two or more, or three or more XRPD signals selected from the group consisting of 11.7°2θ, 18.2°2θ, and 18.9°2θ (±0.2°2θ; ±0.1°2θ; or	12. U.S. Pat. No. US10406123B2 "Binge behavior regulators" Published 10 September 2019. From **page 6, column 8, paragraph 2** "According to some of any of the embodiments of the present invention, **the compound of Formula I is** selected from: 5-methoxy-2-aminoindan; and **5,6-dimethoxy-2-aminoindan**." From **page 14, column 24, paragraph 3** "**Pharmaceutical compositions comprising the compound of Formula I as described herein, may be administered systemically in oral solid** or oral liquid formulations, or as suppository, aerosol, topical or other similar formulations. In preferred embodiments, the binge regulator or a composition comprising same is administered to a subject orally." From **page 13, column 21, paragraph 1** "In any one of the embodiments described herein, each of the compounds described herein can further be in a form of a **pharmaceutically acceptable salt** thereof."

±0.0°2θ; Cu Kα1 radiation).	From **page 13, column 21, paragraph 2** "As used herein, the phrase **"pharmaceutically acceptable salt"** refers to a charged species of the parent compound and its counter-ion, which is typically used to modify the solubility characteristics of the parent compound and/or to reduce any significant irritation to an organism by the parent compound, while not abrogating the biological activity and properties of the administered compound." From **page 13, column 21, paragraph 3** "In the context of some of the present embodiments, **a pharmaceutically acceptable salt of the compounds described herein may optionally be an acid addition salt** comprising at least one basic (e.g., amine) group of the compound which is in a positively charged form (e.g., an ammonium ion), in combination with at least one counter-ion, derived from the selected acid, that forms a pharmaceutically acceptable salt." From **page 13, column 22, paragraph 1** "The **acid addition salts may include** a variety of organic and inorganic acids, such as, **but not limited to, hydrochloric acid which affords a hydrochloric acid addition salt,**..."
337.- 366. (canceled)	
367. A pharmaceutical composition, comprising a solid form according to claim 1, and a pharmaceutically acceptable excipient.	*From the application of interest 17/989,673 paragraph [0004] "N-methyl-3,4-methylenedioxyamphetamine (MDMA), (R)-MDMA, (S)-MDMA, N-ethyl-3,4-methylenedioxyamphetamine hydrochloride (MDE), 5,6-methylenedioxy-2-aminoindane (MDAI), N-methyl-1,3-benzodioxolylbutanamine (MBDB),* ***5-Methoxy-2-aminoindane (MEAI)****,* ***and 5,6-Dimethoxy-2-aminoindane*** *are synthetic analogues of the psychedelic phenethylamine class of compounds. Solid forms of MDMA, (R)-MDMA, (S)-MDMA, MDE, S-MDE, R-MDE, MDAI, MBDB, S-MBDB, R-MBDB, MEAI, or 5,6-Dimethoxy-2-aminoindane, and salts thereof having improved properties are disclosed herein."* 12. U.S. Pat. No. US10406123B2 "Binge behavior regulators" Published 10 September 2019. From **page 6, column 8, paragraph 2** "According to some of any of the embodiments of the present invention, **the compound of Formula I is** selected from: **5-methoxy-2-aminoindan**; and **5,6-dimethoxy-2-aminoindan**." From **page 14, column 24, paragraph 3** "**Pharmaceutical compositions comprising the compound of Formula I as described herein, may be administered systemically in oral solid** or oral liquid formulations, or as suppository, aerosol, topical or other similar formulations. In preferred

	embodiments, the binge regulator or a composition comprising same is administered to a subject orally." From **page 15, column 25, paragraph 2** "**A tablet comprising the active ingredient may**, for example, be made by compressing or molding the active ingredient, optionally with one or more additional ingredients. Compressed tablets may **be prepared by compressing, in a suitable device, the active ingredient in a free-flowing form such as a powder or granular preparation, optionally mixed** with one or more of a binder, a lubricant, **an excipient**, a surface active agent, and a dispersing agent."
368. A method of treating a brain disorder, a neurological disorder and/or a psychiatric disorder in a subject in need thereof, comprising administering to the subject an effective amount of a solid form according to claim 1, or a pharmaceutical composition thereof.	*From the application of interest 17/989,673 paragraph [0535] "Solid form preparations include powders, tablets, pills, **capsules**, cachets, suppositories, and dispersible granules."* *From the application of interest 17/989,673 paragraph [0012] "**The neurological disorder or psychiatric disorder**, or both, may comprise **depression**, addiction, **anxiety**, or a post-traumatic stress disorder, and/or the neurological disorder or psychiatric disorder, or both, may comprise treatment resistant depression, suicidal ideation, major depressive disorder, bipolar disorder, schizophrenia, or substance use disorder. In some embodiments, the neurological disorder or psychiatric disorder, or both, comprises stroke, traumatic brain injury, or a combination thereof."* 13. WOLFSON (2020) "MDMA-assisted psychotherapy for treatment of anxiety and other psychological distress related to life-threatening illnesses: a randomized pilot study" Scientific Reports. Vol. 10:20442. From **page 1** "The success of modern medicine **creates a growing population of those suffering from life-threatening illnesses (LTI) who often experience anxiety, depression, and existential distress**. We present a novel approach; investigating MDMA-assisted psychotherapy for the treatment of anxiety in people with an LTI." From **page 11** "MDMA was manufactured by Dr. David Nichols (Purdue University, West Lafayette, IN, USA). A pharmacist **compounded MDMA or lactose (placebo) into gelatin capsules** to ensure all blinded capsules were similar in appearance and weight." From **page 10** "**These findings provide preliminary evidence to support that MDMA-assisted psychotherapy may be a safe and feasible treatment** for those with LTIs **for anxiety reduction and relief of other psychiatric symptoms** associated with their illness. Study results support the **feasibility of MDMA-assisted psychotherapy as a novel approach for potential long-term treatment of LTI-related anxiety**. These findings will

	inform development of future clinical trials with larger sample size and among more diverse populations."
369.- 376. (canceled)	
377. The method of claim 368, further comprising administering to the subject an effective amount of an empathogenic agent.	*From the application of interest 17/989,673 paragraph [0012] "**The neurological disorder or psychiatric disorder, or both, may comprise depression**, addiction, **anxiety**, or a **post-traumatic stress disorder**, and/or the neurological disorder or psychiatric disorder, or both, may comprise treatment resistant depression, suicidal ideation, major depressive disorder, bipolar disorder, schizophrenia, or substance use disorder. In some embodiments, the neurological disorder or psychiatric disorder, or both, comprises stroke, traumatic brain injury, or a combination thereof."* 1. U.S. provisional document application number 63/250,978 (Filing date 30 September 2021) From **PDF page 12, paragraph [0003]** "In one aspect, the present disclosure provides **pharmaceutical compositions containing a non-racemic mixture of (R)-3,4-methylenedioxymethamphetamine (MDMA) or a pharmaceutically acceptable salt thereof and (S)-MDMA** or pharmaceutically acceptable salt thereof" From **PDF page 13, paragraph [0010]** "In embodiments, the composition of the present disclosure is an oral dosage form. In some embodiments, the **oral dosage form is a tablet or capsule**." From **PDF page 13, paragraph [0013]** "In embodiments, **the patient administered a composition of the present disclosure is treated for symptoms of post-traumatic stress disorder (PTSD).** In embodiments, the patient administered **a composition of the present disclosure is treated for symptoms of generalized anxiety disorder.** In embodiments, the patient administered **a composition of the present disclosure is treated for an eating disorder**." From **PDF page 23, paragraph [0065]** "**Oral pharmaceutical dosage forms can be either solid** or liquid. **The solid dosage forms can be tablets, capsules, granules,** films, (e.g. buccal films) **and bulk powders**." 13. WOLFSON (2020) "MDMA-assisted psychotherapy for treatment of anxiety and other psychological distress related to life-threatening illnesses: a randomized pilot study" Scientific Reports. Vol. 10:20442. From **page 1** "The success of modern medicine **creates a growing population of those suffering from life-threatening illnesses (LTI) who often experience anxiety, depression, and existential distress**. We present

	a novel approach; investigating MDMA-assisted psychotherapy for the treatment of anxiety in people with an LTI." From **page 11** "MDMA was manufactured by Dr. David Nichols (Purdue University, West Lafayette, IN, USA). A pharmacist **compounded MDMA or lactose (placebo) into gelatin capsules** to ensure all blinded capsules were similar in appearance and weight." From **page 10** "**These findings provide preliminary evidence to support that MDMA-assisted psychotherapy may be a safe and feasible treatment** for those with LTIs **for anxiety reduction and relief of other psychiatric symptoms** associated with their illness. Study results support the **feasibility of MDMA-assisted psychotherapy as a novel approach for potential long-term treatment of LTI-related anxiety**. These findings will inform development of future clinical trials with larger sample size and among more diverse populations."
378. The method of claim 368, further comprising administering a 5-HT 2A antagonist to the subject.	*From the application of interest 17/989,673 paragraph [0012] "**The neurological disorder or psychiatric disorder, or both, may comprise** depression, addiction, anxiety, or a post-traumatic stress disorder, and/or the neurological disorder or psychiatric disorder, or both, may comprise treatment resistant depression, suicidal ideation, major depressive disorder, bipolar disorder, schizophrenia, or **substance use disorder.** In some embodiments, the neurological disorder or psychiatric disorder, or both, comprises stroke, traumatic brain injury, or a combination thereof."* 14. U.S. provisional document application number 63/137,615 (Filing date 14 January 2021) From **PDF page 106, claim 1** "A **method of treating an alcohol abuse use disorder** patient in need thereof comprising administering to the patient **a therapeutically effective amount of MDMA** in combination with one or more psychotherapy sessions." From **PDF page 107, claim 11** "The method of any claims 1-10 wherein the alcohol use disorder patient is **also administered a therapeutically effective amount of an additional active agent selected from the group consisting of...5-HT2A receptor antagonist (e.g. quetiapine,** olanzapine, **mirtazapine)**…"
379. The method of claim 378, wherein the 5-HT 2A antagonist is selected from MDL-11,939, eplivanserin (SR-46,349),	*From the application of interest 17/989,673 paragraph [0012] "**The neurological disorder or psychiatric disorder, or both, may comprise** depression, addiction, anxiety, or a post-traumatic stress disorder, and/or the neurological disorder or psychiatric disorder, or both, may comprise treatment resistant depression, suicidal ideation, major depressive disorder, bipolar disorder, schizophrenia, or **substance use disorder.** In some*

ketanserin, ritanserin, altanserin, acepromazine, mianserin, **mirtazapine, quetiapine**, SB204741, SB206553, SB242084, LY272015, SB243213, blonanserin, SB200646, RS102221, nefazodone, MDL-100,907, pimavanserin, pruvanserin, nelotanserin and lorcaserin.	*embodiments, the neurological disorder or psychiatric disorder, or both, comprises stroke, traumatic brain injury, or a combination thereof."* 14. U.S. provisional document application number 63/137,615 (Filing date 14 January 2021) From **PDF page 106, claim 1** "A **method of treating an alcohol abuse use disorder** patient in need thereof comprising administering to the patient **a therapeutically effective amount of MDMA** in combination with one or more psychotherapy sessions." From **PDF page 107, claim 11** "The method of any claims 1-10 wherein the alcohol use disorder patient is **also administered a therapeutically effective amount of an additional active agent selected from the group consisting of...5-HT2A receptor antagonist (e.g. quetiapine,** olanzapine**, mirtazapine)**…"
380.- 401. (canceled)	

Electronic Acknowledgement Receipt

EFS ID:	48588014
Application Number:	17989673
International Application Number:	
Confirmation Number:	7437
Title of Invention:	PHENETHYLAMINE COMPOUNDS SALTS, POLYMORPHIC FORMS AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Matthew DUNCTON
Customer Number:	58249
Filer:	Shahin Shams
Filer Authorized By:	
Attorney Docket Number:	STBI-039/C01US331775-2179
Receipt Date:	14-SEP-2023
Filing Date:	17-NOV-2022
Time Stamp:	15:20:53
Application Type:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	51580 3258246c2ce416cc5d7af43d9a22829ba7f95d82	no	11

Warnings:

Information:					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	75723 219700b575662160798a90f37b64dfdf97da0b66	no	5
Warnings:					
Information:					
3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23719 d29685450e1a5e929f645a1e6c1ce34a9c1f30d9	no	1
Warnings:					
Information:					
4	Concise Description of Relevance	US20230202998ClaimChartUPDATEDComp.pdf	407357 378621d00312ad57b1d02c9dbd38f0fd6e46edeb	no	31
Warnings:					
Information:					
5	Evidence of Publication	1-63250978Provisional.pdf	2759121 477244255d487873af84adb39837bee7cc08f2ca	no	38
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6	Evidence of Publication	2-63184703Provisional.pdf	1881364 6ee11511633d6ddf86692eff67ca0fc7b9ab1293	no	26
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Information:					
7	Evidence of Publication	3-EROWID.pdf	677775 64c7c3629eca2ab243d957d6ee62267720e34624	no	2
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Information:					
8	Evidence of Publication	4-EROWID.pdf	218248 9178b48d9f28f6dd5680884440ade778e8aaf935	no	1
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9	Evidence of Publication	5-EROWID.pdf	202625 a1118b36a9e29a5988e23afc33d50c47e0d4b4a2	no	1
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10	Evidence of Publication	6-SHULGIN.pdf	170334 01bc2243b7a0aec1c5e75cde7b391e10653aa75b	no	2
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Information:					
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12	Evidence of Publication	8-ZOOMGROOVE.pdf	252353 47b22166d69c9617da0e57130c7863ef7e907cd1	no	2
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13	Evidence of Publication	9-SHULGIN.pdf	171553 796a41c4bde5221e7495d793c7f9b0664c8a2cfb	no	2
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14	Evidence of Publication	10-MURPLE.pdf	206391 b7b75d4625c4ecdcf1f359a93396d129163cc8a1	no	2
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		Total Files Size (in bytes):	7273771		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Electronic Acknowledgement Receipt

EFS ID:	48588185
Application Number:	17989673
International Application Number:	
Confirmation Number:	7437
Title of Invention:	PHENETHYLAMINE COMPOUNDS SALTS, POLYMORPHIC FORMS AND METHODS OF USE THEREOF
First Named Inventor/Applicant Name:	Matthew DUNCTON
Customer Number:	58249
Filer:	Shahin Shams
Filer Authorized By:	
Attorney Docket Number:	STBI-039/C01US331775-2179
Receipt Date:	14-SEP-2023
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Time Stamp:	15:32:43
Application Type:	

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Concise Description of Relevance	Concise-description-generated.pdf	48233 66b405719bfb790801820e4a6effc5047930b00e	no	9

Warnings:

Information:					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	72849 5d918a9a1357ee4447d927d3ba3f42b755abbe37	no	5
Warnings:					
Information:					
3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23721 b9bd55f6d87c42d7845336df8e00fafbbd4815fb	no	1
Warnings:					
Information:					
4	Concise Description of Relevance	US20230202998ClaimChartUPDATEDComp.pdf	407357 378621d00312ad57b1d02c9dbd38f0fd6e46edeb	no	31
Warnings:					
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5	Evidence of Publication	11-63236498Provisional.pdf	4313511 e79838d1b57f432f9334ba7e3a2d366d06c8630a	no	57
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Information:					
6	Evidence of Publication	12-US10406123B2.pdf	2305202 5063abfea3e244242fb1209eb4339b57ca3642a6	no	19
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Information:					
7	Evidence of Publication	13-WOLFSON.pdf	1093263 34df8d2afe17cfd9f6aa292a1b28d1bd58fef6e3	no	15
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8	Evidence of Publication	14-63137615Provisional.pdf	8299480 8ee5dab8113dc7b64cfd014e6a551cf62448afbf	no	111
Warnings:					
Information:					

9	Evidence of Publication	15-CORKERY.pdf	145041 d38f35efcd7e8496e9e0b8b4e54619dc71ff34d9	no	11
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Information:					
10	Evidence of Publication	16-PUBCHEM.pdf	317088 19fbf1796728f0464763f254174d1501fc753b2f	no	11
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11	Evidence of Publication	17-PUBCHEM.pdf	258037 c98e3ab9fc4b32eebb6e974bbce7e9557437fc9e	no	8
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Information:					
12	Evidence of Publication	18-RENDLE.pdf	184808 62fc2fbaa5e53f496d0a5a31bf0059dc050b65fe	no	3
Warnings:					
Information:					
13	Evidence of Publication	19-RESEARCHGATE.pdf	1056778 d3c2cf96f7cfda2284281bf7e6afaa06811f8dd4	no	8
Warnings:					
Information:					
		Total Files Size (in bytes):	18525368		

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New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.